K131919

ZOLL®

DEC 17 2013

ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824
U.S.A.

978-421-9655
978-421-0025 Main Fax

510(k) Summary:

Submitter's Name and Address:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

Contact Person:

Shannon Duhamel

(978) 421-9574

Date Summary Prepared:

June 24, 2013

Device:

ZOLL ePCR iOS

Classification:

Classification Product Code:

21 CFR 870.2450. Display, Cathode Ray Tube, Medical. Product code: DXJ. Device Class: 2.

Secondary Product Code:

Software, Transmission and Storage, Patient Data. Product code: NSX. Device Class: Not Classified.

Description:

The proposed ZOLL ePCR iOS is a software-only product. ZOLL ePCR iOS is a medical data collection system used to collect, store and print patient data that is entered by a user (caregiver), or captured from specified medical devices, and integrated into a patient care report (patient electronic medical record). ZOLL ePCR iOS is non-alarming software that runs on various iOS devices (iOS is the Apple operating system for use on iPads and iPhones).

Intended Use:

ZOLL ePCR iOS is intended for the collection, storage and printing of patient data that is entered by a user (caregiver), or captured from specified medical devices, and integrated into a patient care report (patient electronic medical record). ZOLL ePCR iOS is intended for use by qualified medical personnel providing direct patient care in the pre-hospital environment to document the care provided. ZOLL ePCR iOS is indicated for use by health care providers whenever there is a need for generation of a patient record.

Substantial Equivalence:

The features and functions of the proposed ZOLL ePCR iOS are substantially equivalent to the predicate device, ZOLL RescueNet ePCR (K103473), cleared for use on 05/13/2011.

Comparison of Technological Characteristics

ZOLL ePCR iOS features and functions are similar to the predicate device, Zoll RescueNet ePCR, except that the proposed device uses a different operating system. ZOLL ePCR iOS is a software application designed for use on iOS devices whereas the indicated predicate device operates on a tablet or web-based Microsoft Windows system.

Both ZOLL ePCR iOS and the indicated predicate device are software-only products intended for the collection, storage and printing of patient data, including data that is entered by a user (caregiver) and data collected from other medical devices. Both ZOLL ePCR iOS and the indicated predicate device are indicated for use by health care providers whenever there is a need for generation of a patient record. Both the proposed device and the indicated predicate device are designed to synchronize to a data server using a wireless or network connection to import or access saved PCRs for completion at a convenient time. No new issues of safety or effectiveness are raised by this premarket notification.

Performance Testing:

Extensive performance testing ensures that ZOLL ePCR iOS performs as well as the indicated predicate device and meets all of its functional requirements and performance specifications.

Conclusion

The information provided in this 510(k) submission demonstrates that the features and functions of the proposed ZOLL ePCR iOS are substantially equivalent to the corresponding features and functions of the indicated commercially distributed predicate device with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 17, 2013

ZOLL Medical Corporation
Ms. Shannon Duhamel
Regulatory Affairs Specialist
269 Mill Road
Chelmsford, MA 01824

Re: K131919
Trade/Device Name: ZOLL ePCR iOS
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: II
Product Code: DXJ, NSX
Dated: November 21, 2013
Received: November 22, 2013

Dear Ms. Duhamel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K131919

Device Name: ZOLL ePCR iOS

Intended Use:

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Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Richard C. Chapman
Date: 2013.12.17
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